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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/031,478

07/29/2002

Kevin Jeffrey Barnham

16153

8704

23389

7590

05/01/2009

SCULLY SCOTT MURPHY & PRESSER, PC
400 GARDEN CITY PLAZA
SUITE 300
GARDEN CITY, NY 11530

EXAMINER

KOSAR, ANDREW D

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

05/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/031,478	Applicant(s) BARNHAM ET AL.	
	Examiner ANDREW D. KOSAR	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 56-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 56-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's petition to revive was granted on March 12, 2009.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 6, 2008 has been entered.

Response to Amendments/Arguments

Applicant's amendments and arguments filed November 6, 2008 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below in original or modified form is herein withdrawn.

Applicant's amendments have overcome the outstanding rejections, thus necessitating the search be extended with the genus. Claims 56-71 are pending and have been examined on the merits.

Claim Objections

Applicant is advised that should claim 61 be found allowable, claim 68 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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Claim Rejections - 35 USC § 112The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 69-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 69-71 lack clear antecedent basis, as there is not support in the claim from which they depend for the “targeting moiety”.

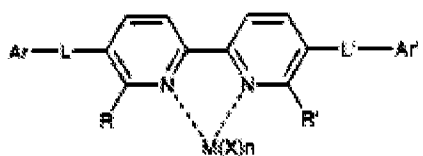
Claim Rejections - 35 USC § 102The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 56-61 and 66-68 are rejected under 35 U.S.C. 102(b) as being anticipated by LANSBURY (WO 97/41856 A1).

Lansbury teaches treating Alzheimer’s disease with 2,2’-bipyridine compounds, e.g.



, where M can be Cd, Co, Cu and Ni (as instantly claimed), or

Zn, Fe, or ^{99}Tc , ^{111}In , ^{90}Y or ^{186}Re (e.g. claims 1 and 75-87). Because there are so few species of metal claimed in Lansbury, and the instant claims have no specific 2,2’-bipyridine complex claimed, one could at once envisage each and every species of complex, and the claims are anticipated. Furthermore, it is inherent that because the structural limitations are met, the instant functional requirements necessarily are present.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 56-64 and 66-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over LANSBURY (WO 97/41856 A1), *supra*, in view of PARDRIDGE (US 5,004,697; PTO 892, 6/20/07).

The claims are further drawn to the compound having a targeting moiety.

As stated in previous Office Actions, Pardridge teaches modifying antibodies for delivery through the BBB for neuropharmaceuticals (e.g. Abstract, claims 6 and 9), specifically teaching that the antibody is for amyloid peptide of Alzheimer's disease (claim 9).

The difference between the instant claims and the teachings of Lansbury, is that while Lansbury teaches treating Alzheimer's with a metal bipyridine complex, Lansbury does not teach coupling it with a targeting moiety.

It would have been obvious to have made and delivered the bipyridine complex via coupling to an amyloid specific antibody in order to specifically deliver the complex to the Alzheimer's plaques it is used to treat. One would have been motivated to have coupled the bipyridine to an antibody in order to deliver it efficiently to the point of need. One would have had a reasonable expectation for success in making the complex-antibody conjugate, as conjugation of antibodies to therapeutics is a technique widely practiced in the medicinal arts, particularly to cross the BBB (as cited previously, e.g. Saito, et al. PNAS (1995) 92, pages 10227-10231).

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A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 56-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over LANSBURY (WO 97/41856 A1), *supra*, in view of PARDRIDGE (US 5,004,697; PTO 892, 6/20/07), as applied to claims 56-64 and 66-71, *supra*, and in further view of PROKOPCHUK (E.M. Prokopchuk et al. Organometallics. (1999) 18(15), pages 2861-2866).

The claims are further drawn to where the metal is Pt. While Lansbury teaches a variety of metal complexes that are taught to be useful for treating Alzheimer's, Lansbury does not teach Pt as the metal.

Prokopchuk teaches platinum 2,2'-bipyridine complexes, as well as 1,10-phenanthroline complexes (e.g. Chart 1, page 2861).

It would have been obvious to have used any metal, including Pt in the complex, as Lansbury teaches a variety of transition metals that are capable of being used in the complex, spanning the range of transition metals with a variety of oxidation states. One would have been motivated to have used any transition metal, including Pt, as transition metal bipyridine

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complexes are ubiquitous in the art, making them generally available to the artisan. Given that Ni, Pd, and Pt are in the same period, and that Lansbury explicitly contemplated a variety of transition metals, including Ni and other elements sharing similar oxidation states to Pt (and the other claimed transition metals), one would reasonably expect any transition metal would function in the complex of Lansbury to treat Alzheimer's.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW D. KOSAR whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/

Primary Examiner, Art Unit 1654